

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No. 06-222 (JJF)

**OPPOSITION OF IMPAX LABORATORIES
TO WYETH'S MOTION TO STRIKE
THE EXPERT REPORT OF MARK E. NUSBAUM**

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I. INTRODUCTION

Wyeth's motion to strike the expert report of Mark E. Nusbaum is untimely and inappropriate at this stage of the proceeding. Not only are expert reports still being submitted and expert discovery still proceeding, but *fact* discovery is open and on-going. The Court should not make a premature decision as to what testimony will be allowed at trial, given that fact and expert discovery is underway and the issues for trial are not yet determined. At a minimum, the Court should deny Wyeth's motion without prejudice to renew as appropriate at a later time. Should the Court decide to reach the merits of Wyeth's motion, Mr. Nusbaum's expert report is appropriate and not precluded by the Court's guidelines for patent law experts, and Wyeth's motion should be denied on this basis as well.

II. ARGUMENT

A. Wyeth's Motion is Untimely and Inappropriate

Wyeth's motion should be denied because it is untimely and inappropriate. Motions to strike or limit an expert's testimony are properly made close to the time of trial, when the issues for trial have narrowed and crystallized through the pre-trial process and the Court's rulings on summary judgment motions and claim construction disputes. It is inappropriate to move to strike now, long before summary judgment, when expert rebuttal reports are still to be submitted, no expert depositions have been taken, and fact discovery is on-going. The Court cannot make a determination as to whether a given expert's testimony will be of assistance until it knows the issues for trial.

Motions to exclude all or a portion of an expert's testimony are usually made as motions *in limine* or as part of a pre-trial conference. The cases cited by Wyeth reinforce and support this practice. No case cited by Wyeth supports striking an expert's opening report before rebuttal reports are submitted, before expert depositions are taken, and even before fact discovery closes. Wyeth cites to *L'Oreal S.A. v. Revlon Consumer Prods. Corp.*, C.A. No. 98-424-SLR (D. Del. Feb. 24, 2000),¹ where the motion on expert testimony was filed as a motion *in limine* just before

¹ Wyeth's Opening Brief, Ex. D at 1, 3 ("Op. Br.").

trial; *Lucas Aerospace, Ltd. v. Unison Indus., L.P.*, C.A. No. 93-525-JJF (D. Del. Mar 9, 1995)² was the same – a motion *in limine*, as was *Software AG v. BEA Sys., Inc.*, C.A. No. 03-739-GMS (D.Del. Apr. 8, 2005).³ Similarly, in *Corning Inc. v. SRU Biosystems*, C.A. No. 03-633-JJF (D. Del. Nov. 5, 2004),⁴ the motion was filed after expert reports were submitted and expert depositions concluded, and the court ruled at the pre-trial conference just before trial. In *Revlon Consumer Prod. Corp. v. L'Oreal S.A.*, 1997 U.S. Dist. LEXIS 4117 (D. Del. Mar. 26, 1997), the Court ruled after the close of expert and fact discovery and during summary judgment briefing.⁵ Continuing in the same vein, in *Ondeo Nalco Co. v. EKA Chems., Inc.*, C.A. No. 01-537-SLR (D.Del. Mar. 21, 2003)⁶ the Court ruled as part of summary judgment. Taking the concept to its logical conclusion, the Court in *Thorn EMI N. Am. Inc. v. Micron Tech., Inc.*, C.A. No. 92-673-RRM (D.Del. Nov 23, 1993)⁷ addressed the motion at the pre-trial conference, but did not forbid or strike any testimony, reserving the final decision on admissibility for trial itself. All of these cases reflect the prevailing practice and wisdom of ruling on the admissibility of expert testimony close to or during trial – not in the middle of discovery.⁸

Courts rule on the admissibility of expert testimony near the time of trial for good reason. By the time of trial, some issues have been resolved or discarded and no longer require testimony; the parties have reached agreements on the scope of some testimony; and the overall scope of the trial testimony is clearer, including the relations between various testifying experts.

² Op. Br., Ex. E at 1.

³ Op. Br., Ex. I at 3:1-2; see Docket, *Software AG v. BEA Sys., Inc.*, C.A. No. 03-739-GMS at D.I. Nos. 175 and 180, Ex. 5 of Matterer Decl.

⁴ Op. Br., Ex. H at 2; see Docket *Corning Inc. v. SRU Biosystems*, C.A. No. 03-633-JJF, Ex. 3 of Matterer Decl.

⁵ See Docket, *Revlon Consumer Prod. Corp. v. L'Oreal S.A.*, C.A. No. 96-CV-00192-MMS at D.I. Nos. 183, 184, Ex. 4 of Matterer Decl.

⁶ Op. Br., Ex. C at 8-9, 17.

⁷ Op. Br., Ex. F at 13:5-14.

⁸ Wyeth cites to one case that involves an earlier ruling, *F.Hoffman-LaRoche v. IGEN Int'l Inc.*, C.A. No. 98-318-JJF (D. Del. Oct 24, 2000) (Op Br., Ex. G). There, one party objected pursuant to the terms of the protective order to the disclosure of its confidential information to a proposed expert and consultant of the opposing party. Here, Impax disclosed Mr. Nusbaum under the protective order a long time ago, and Wyeth made no objections.

To determine admissibility, a court is guided by Federal Rule of Evidence 702, which states that an expert may testify if it will “assist the trier of fact.” A court can better determine what will assist the trier of fact much more easily closer to trial rather than earlier; such a decision cannot be made until the issues are known. Moreover, sometimes the parties obviate the need for court intervention and reach agreement. For instance, in *L’Oreal S.A. v. Revlon Consumer Prods. Corp*, the motion to limit the scope of expert testimony was unopposed, and the Court allowed the expert to testify as to PTO practice and procedure.⁹

In this case, Wyeth’s motion is particularly premature. Opening expert reports were submitted on September 28, 2007; rebuttal reports have not yet been submitted. No expert depositions have taken place. Moreover, fact discovery is on-going – Wyeth is still producing documents, having produced documents three times so far since opening expert reports were submitted.¹⁰ Wyeth still has not proffered all its Rule 30(b)(6) witnesses, which the Court ordered months ago. (Wyeth just recently offered its last Rule 30(b)(6) deponent for November 30, 2007 – two months after the submission of opening expert reports, and the day on which summary judgment motions are due).¹¹ Additionally, third-party document productions and depositions are still on-going.¹² This continuing fact discovery already has necessitated supplemental expert reports to take into account these new facts, including a supplemental Nusbaum report.¹³ More supplemental reports may be required based on additional fact discovery. For Wyeth to be moving to strike an opening expert report at this early stage is

⁹ Op. Br., Ex. D at 3.

¹⁰ Wyeth recently produced documents on October 1, October 12 and October 19, 2007, including production of the Alza re-examination request, which Impax had requested on July 21, 2007.

¹¹ See October 24, 2007 Letter to Barbara R. Rudolph from Joseph C. Gratz regarding 30(b)(6) deponent, attached as Ex. 1 to the Declaration of Mary B. Matterer Re Opposition of Impax Laboratories To Wyeth’s Motion to Strike the Expert Report of Nusbaum (“Matterer Decl.”).

¹² For instance, after the submission of opening expert reports, Alza Corp. was deposed on October 11, 2007, IMS was deposed on October 9, 2007, and Mr. DeNeale, a former Wyeth employee, is due to be deposed on Nov. 8.

¹³ Impax submitted a supplemental expert report for Dr. Kibbe on October 22, 2007 and Mr. Nusbaum on October 23, 2007.

inappropriate and premature.

As fact discovery comes to a close, expert reports are submitted, and expert depositions concluded, the issues in the case will crystallize. The parties will further narrow and refine their issues through their pre-trial filings, such as lists of contested issues of fact and law, statements of intended proofs and trial exhibits, and witness lists. At that time, the parties can meet and confer on many issues, including the scope of expert testimony. The parties may, like the parties in *L’Oreal*, reach agreement that would make the Court’s intervention unnecessary. Additionally, the Court may rule on claim construction or summary judgment and further narrow the issues for trial.

Should the parties not be able to reach agreement, Wyeth would be free to bring any remaining issues concerning the scope of expert testimony as a motion *in limine*. At or near trial, the Court could properly assess the proffered expert testimony, consider it in light of the issues for trial and the other experts, and make an appropriate determination as to admissibility.

B. Nusbaum’s expert report is appropriate and within the Court’s guidelines

Mr. Nusbaum’s opening report, as well as his supplemental report,¹⁴ contain appropriate material within the Court’s prior practice and guidelines regarding patent law experts. Mr. Nusbaum’s reports include material on patent office practice and procedure (sect. II), prosecution histories of the patents-in-suit (sect. III), and the duty of disclosure (sect. IV). These are appropriate subjects for his report.

Because the admission of expert testimony is a “procedural matter” not unique to patent issues, the law of the Third Circuit governs. *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574-75 (Fed. Cir. 1984), *accord Nat’l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1188 n.2 (Fed. Cir. 1996). Federal Rule of Evidence 702 governs expert testimony: “If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness … may testify thereto in the form of an

¹⁴ Mr. Nusbaum’s supplemental report is attached as Ex. 2 of the Matterer Decl. The supplemental report contains the same material as the original report, along with additional material based on recent discovery.

opinion or otherwise.” The Third Circuit has given a broad interpretation to Rule 702: close calls on the admission of expert testimony are to be resolved in favor of admissibility. *Dunn v. HOVIC*, 1 F.3d 1362, 1367 (3d Cir. 1993).

This Court has allowed expert testimony on patent office practice and procedure. In *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 2006 WL 2241018 (D.Del. Aug. 4, 2006), the Court allowed testimony on “PTO practice and procedures.” Similarly in *Revlon Consumer Prod. Corp. v. L’Oreal S.A.*, 1997 WL 158281 (D. Del. Mar. 26, 1997), the parties agreed that the expert could testify as to PTO practice and procedure, and the Court did not dispute the appropriate nature of this testimony and allowed it. Again in *Lucas Aerospace, Ltd., v. Unison Industries, L.P.*, C.A. No. 93-525-JJF (D.Del. Mar 9, 1995),¹⁵ this Court allowed patent law expert testimony on patent office practice and procedures.

Courts in other jurisdictions similarly allow patent law experts to testify as to patent office practice and procedure. In *Pinpoint Inc. v. Amazon.com, Inc et al.*, 2004 U.S. Dist. LEXIS 24694 (Nov. 19, 2004), the court addressed each party’s motions *in limine* to limit the testimony of patent law experts. *Id.* at *4-5. The court held that “if evidence is not clearly inadmissible, evidentiary rulings must be deferred until trial to allow questions of foundation, relevancy and prejudice to be resolved in context.” *Id.* Addressing the experts’ lack of experience in the art, the court held that an “attorney’s lack of technical expertise goes to the weight of his testimony, not its admissibility.” *Id.* at *10. The court allowed each party’s expert to testify as to “PTO procedures, including PTO’s reliance on the duty of disclosure and practices in familiar prosecutions.” *Id.* Similarly in *Cameco Indus. v. Louisiana Cane Mfg.*, 1995 U.S. Dist. LEXIS 11294, *8-11 (E.D. LA July 28, 1995), the court allowed a patent lawyer to provide expert testimony to rebut defendant’s inequitable conduct defense, notwithstanding the fact that the proffered expert had no technical expertise in the art. The court in *Chamberlain Group, Inc. v. Interlogix, Inc.*, 2002 U.S. Dist. LEXIS 6998 *2-4 (N. D. Ill. April 19, 2002) denied a motion to strike an expert report in part because the expert’s expertise in PTO procedures may be helpful to the trier of fact, finding that the PTO examiners’ specialized knowledge means that their

“[e]xpert testimony on prior art, prosecution history, and PTO operations can be helpful to an understanding of the issues in a patent infringement action.” *Id. at *3-4* (citing *Yarway Corp. v. Eur-Control United States*, 775 F.2d 268, 274 (Fed. Cir. 1985)). Additionally in *3M v. Appleton Papers*, 1998 U.S. Dist. LEXIS 22597, *6-7 (D. Minn. June 25, 1998) and *Bausch & Lomb, Inc. v. Alcon Labs, Inc.*, 79 F. Supp. 2d 252, 255-56 (W.D.N.Y. 2000) the court allowed testimony regarding PTO practice and procedure.

This Court’s *Guidelines: Legal Expert Testimony in Patent Cases* does not dictate a contrary result. First, the *Guidelines* discusses patent jury trials, and the practice of showing the Federal Judicial Center video overview of the patent system. Here, this case is a bench trial, not a jury trial. The Court has the flexibility to allow whatever testimony it believes will be helpful, consistent with Rule 702, based on the issues and the other testimony to be presented at trial. As the Federal Circuit has stated concerning proffered patent law testimony, the lower court “has complete discretion to adopt the expert legal opinion as its own, to find guidance from it, or to ignore it entirely, or even to exclude it.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983 (Fed. Cir. 1995).

Mr. Nusbaum’s testimony may be helpful to the Court in several ways. Mr. Nusbaum explains and highlights the sections of the patent prosecution histories upon which Impax intends to rely. Since this is a bench trial, and the Court is undoubtedly familiar with certain aspects of PTO practice and procedure already, Mr. Nusbaum’s testimony could quickly pinpoint those particular sections of the many applications, continuations-in-part, provisional applications and the reexamination that are important to Impax’s case.

The Alza reexamination, in particular, might benefit from explanatory testimony. In that reexamination, Wyeth asked the PTO to reexamine U.S. Patent No. 6,440,457, which claims a wide range of extended release dosage forms of venlafaxine. Wyeth’s reexamination request, which is still unresolved, claims that the '457 patent should be rejected as obvious because of the PTO’s treatment of United States Patent Application No. 08/442,292, a child application to the application that ultimately issued as the '457 patent. The reexamination request argues that the

¹⁵ Op. Br., Ex. E.

Board of Patent Appeals and Interferences, remanding to the examiner in Appeal No. 2005-1829, directed the examiner to take "consistent action" with regard to the '292 Application and the application that ultimately issued as the '457 patent. Because the examiner rejected the '292 application on obviousness grounds but allowed the '457 patent to issue, the '457 patent should be reexamined, Wyeth argues in its request, as the examiner failed to properly implement the instructions of the Board of Patent Appeals and Interferences on remand. Perhaps most importantly, this logic applies equally well in this case to defeat Wyeth's arguments regarding the nonobviousness of the patents-in-suit.

Mr. Nusbaum may also testify as to the duty of disclosure and materiality. Here, Mr. Nusbaum could point out which sections of the Manual of Patent and Examining Procedure (MPEP) Impax relies on. Moreover, Mr. Nusbaum can explain the materiality of Wyeth's failure to disclose information inconsistent with its alleged "improvement," and Wyeth's failure to disclose Alza's prior art formulation (and the relation of that failure to the current re-examination request). Lastly, Mr. Nusbaum could explain the materiality of Wyeth's failure to name the correct inventors of two of the patents-in-suit.

Wyeth also complains that Mr. Nusbaum relies on other experts. But reliance on other experts is permitted. An expert may rely on any information "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences." Fed. R. Evid. 703. Because "[a]n expert cannot be an expert in all fields . . . it is reasonable to expect that experts will rely on the opinion of experts in other fields as background material for arriving at an opinion." *United States v. 1014.16 Acres of Land*, 558 F. Supp. 1238, 1242 (W.D. Mo. 1983), *aff'd*, 739 F.2d 1371 (8th Cir. 1984). This is particularly true in a complex and technical patent-infringement action such as this one. Nusbaum is entitled to rely on the opinion of Impax's technical expert in reaching his conclusions. Indeed, Wyeth's experts rely extensively on each other as well; Dr. McGinity relies on Dr. Sawchuck and on Dr. Hollander, ¶¶51-53; Dr. Sawchuck relies on Dr. Thisted, pg. 43; and Dr. Sawchuck relies on Dr. Hollander, pp 46-48.

The Nusbaum expert report contains appropriate subject matter at this stage. The report provides the spectrum of possible testimony for Mr. Nusbaum, some of which may ultimately be

offered at trial and some of which may not, depending on discovery and the narrowing of issues before trial. Indeed, if the report were not as complete as it is, Wyeth might well later argue that it was not on notice as to Impax's theories of inequitable conduct. In *Abbott Labs. v. Syntron Bioresearch, Inc.*, 2001 WL 34082555, *5 (S.D. Cal. Aug. 24, 2001), the plaintiff moved to exclude the defendant's untimely defense of inequitable conduct because while the defense was raised in the pleadings, it had not been raised in the expert reports.

III. CONCLUSION

For the reasons set forth above, Impax requests that the Court deny Wyeth's untimely and inappropriate Motion to Strike Mr. Nusbaum's expert report.

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